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Why ICD Patients With Heart Failure (Class II-IV) Are Hospitalized: Do the Reasons Differ for Patients Who Are Treated With Cardiac Resynchronization Therapy?

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Background: Cardiac resynchronization therapy (CRT) is currently being tested as an adjunct therapy to treat heart failure (HF). The VENTAK CHF/CONTAK CD study, a multicenter double-blind study, enrolled patients with HF who also met the general indications for an ICD. It is not known if this HF population that also requires an ICD is hospitalized for different reasons than the HF population as a whole or if CRT changes the rate or reasons for hospitalization.

Methods: 501 patients (Age: 66 ± 10 years, QRS: $158 \text{ ms} \pm 26$, NYHA Class III 58%, LVEF $21.5 \pm 6.6\%$, Ischemic etiology 68.9%) were implanted with a CRT/ICD system and were randomized to CRT or no CRT. The reason for all hospitalizations were adjudicated by an independent events committee that was blinded to pacing mode, and were classified as CHF related, other cardiac or non-cardiac.

Results: There were 231 hospitalizations for ICD patients with symptomatic HF. The addition of CRT did not significantly change the rate of hospitalizations or the reasons for being hospitalized.

Reason for Hospitalization	CRT		No CRT		Total	
	Patients	Events	Patients	Events	Patients	Events
CHF	32	50	39	56	71	106
Cardiac - other	20	40	25	31	45	71
Noncardiac	26	30	19	24	45	54
Total	66	120	70	111	136	231

Conclusion: CRT does not effect the frequency or reason of hospitalization in patients with heart failure receiving an ICD. The most common reason for hospitalization is heart failure.

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Long-Term Improvement in Functional Status, Quality of Life and Exercise Capacity With Cardiac Resynchronization Therapy: The MIRACLE Trial Experience

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Background: Moderate-to-severe Congestive Heart Failure (CHF) patients (pts) with a prolonged QRS duration ($>130 \text{ ms}$) enrolled in the Multicenter InSync Randomized Controlled Evaluation (MIRACLE) Trial improved their functional status, quality of life and exercise tolerance during a 6 month double-blind evaluation of cardiac resynchronization therapy (CRT). The purpose of this analysis is to examine the long-term impact of CRT on the endpoints of Six-minute Hall Walk Distance (HWK), Minnesota Living with Heart Failure Quality of Life Score (QOL), NYHA Functional Class (NYHA) and Exercise Duration (EXT) on a Treadmill.

Methods: Pts that received 12 months of CRT in the MIRACLE trial were included in this evaluation. Endpoints were assessed using pts as their own controls. All tests of significance are based on the Wilcoxon Signed Rank Test.

Results: 67 pts received CRT for a period of 12 mos (mean age(years): 62.4 ± 11.7 ; LVEF (%): 22.4 ± 5.8 ; LVEDD (mm): 69.7 ± 10.5 ; 75% male; QRS duration (ms): 164 ± 18 . Improvements in HWK, QOL, NYHA and EXT from baseline to 6 months and baseline to 12 months are shown in the Table.

Endpoint	Baseline to 6 months	p-value	Baseline to 12 months	p-value
	Median Change (inter-quartile range)		Median Change (inter-quartile range)	
HWK (meters)	61.5 (15.6,107.7)	< 0.001	42.8 (-15.1, 115.6)	<0.001
QOL score	- 22.5 (-42, -5.7)	< 0.001	-18 (-43.5, -7)	< 0.001
NHYA class	- 1.0 (-1.0, 0)	< 0.001	-1.0 (-2.0, -1.0)	< 0.001
EXT (seconds)	120.5 (40, 195)	< 0.001	106 (14, 216)	0.007

In addition, 57 pts originally randomized to the no-CRT group for the first 6 months of the study subsequently received 6 months of CRT. HWK, QOL, NYHA and EXT were all improved at 12 months as compared to Baseline ($p < 0.05$).

Conclusions: In pts with symptomatic CHF, systolic dysfunction and a prolonged QRS, CRT offers a sustained, long term improvement in patient well-being and exercise capacity.

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Lower Sinus Rate After Initiation of Left Ventricular Pacing in Patients With Left Bundle Branch Block and Advanced Heart Failure

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The hypothesis was that the improvement of left ventricular pacing in patients with advanced heart failure and left bundle branch block is associated with changes of sinus rate. The distribution of the sinus rate at month 1 stored in the rate histogram of the pacemaker was compared to the findings at month 12. The study included 31 patients with advanced heart failure and left bundle branch block. All patients received a specially designed pacing lead, which was placed in a side branch of the coronary sinus for left ventricular pacing. The lead was connected to a DDD pacemaker (Affinity DR, St. Jude Medical) in 8 and to a biventricular three-chamber pacemaker (Frontier 3x2, St. Jude Medical) in 23 patients. The pacemaker stored in the diagnostic counters the atrial rate histogram, which summarizes the heart rates from 55 to 70 bpm (H1), from 71 to 90 bpm (H2), from 91 to 110 bpm (H3), and from 110 to 131 bpm (H4).

RESULTS: The patients had at implantation NYHA class III ($n = 9$) or class IV ($n = 22$). Follow-up at month 12 is completed in 19 patients who had NYHA class I in 15 and class II in 4 patients. At hospital discharge, 25 patients were programmed to the DDD and 6 patients to the DDDR mode. Lower pacing rate was programmed to 62 ± 8 ppm and upper pacing rate to 113 ± 4 ppm. Besides the reduction of diuretics there was no relevant modification of the prescribed medication. The percentage of atrial pacing was $26 \pm 41\%$ of the time at month 1 and $35 \pm 45\%$ of the time at month 12. The distribution of the atrial rate was at month 1 $55 \pm 20\%$ (H1), $39 \pm 18\%$ (H2), $5 \pm 2\%$ (H3), $2 \pm 1\%$ (H4), and at month 12 $78 \pm 21\%$ (H1; $p < 0.05$ vs month 1), $17 \pm 15\%$ (H2; $p < 0.05$ vs month 1), $4 \pm 3\%$ (H3), and $1 \pm 1\%$ (H4). The DDDR mode was programmed in additional 4 patients because of chronotropic incompetence during follow-up. There were no significant differences between patients with left and biventricular pacing.

CONCLUSIONS: There was a significant 45% decrease in the frequency from 71 to 90 bpm and a significant increase in the frequency from 55 to 70 bpm during the first year follow-up. The findings indicate that the symptomatic improvement after left ventricular pacing is associated with lower sinus rate.

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Detectable Troponin T Level Predicts High Mortality in Patients With Heart Failure Undergoing Internal Defibrillator Implantation

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Background: Troponin levels have been demonstrated to predict cardiac events in patients with ischemic as well as non-ischemic cardiomyopathy (CM). Arrhythmic death remains a leading cause of mortality in patients with CM. While implantable cardiac defibrillator (ICD) devices have been demonstrated to favorably impact mortality in certain subsets of patients with CM, their mortality remains high.

Methods: In an effort to study the predictive value of baseline troponin levels in patients who are candidates for ICD devices we collected baseline blood samples for troponin T (TnT) and CK-MB in 52 consecutive patients immediately before successful pectoral transvenous ICD implant. Patients with any clinical evidence of an acute coronary syndrome during the preceding 2 weeks were excluded from the study. All patients received ICDs for standard clinical indications. They subsequently received routine clinical follow up care. Patients were divided into two groups based on their TnT level prior to implantation. Patients with non-detectable TnT ($<0.01 \text{ ng/ml}$) were classified as Group A. Patients with detectable TnT ($\geq 0.01 \text{ ng/ml}$) were classified as study Group B. Patients were then followed for total mortality.

Results: All patients were males with mean age 68 ± 10 years. Mean ejection fraction was $29 \pm 12\%$ and 65% had ischemic cardiomyopathy. Mean follow up duration was 17 ± 8 months. None of the patients had abnormal CK-MB mass (Mean $1.7 \pm 1.1 \text{ ng/ml}$). There were 37 patients in Group A and 15 patients in Group B (TnT $0.013 \pm 0.146 \text{ ng/ml}$). There was no difference between the groups A and B in terms of age (68 vs. 69, $p = \text{NS}$), ejection fraction (30 vs. 29%, $p = \text{NS}$) or proportion of patients with ischemic cardiomyopathy (68 vs. 60%, $p = \text{NS}$). There were no early post-operative deaths (within 30 days). During follow up 16 (31%) patients died. Group A patients had 16% mortality (6/37) compared to 67% mortality (10/15) in Group B ($p < 0.001$).

Conclusions: In a cohort of male patients with CM undergoing ICD implantation for standard clinical indications, presence of detectable TnT is associated with high mortality despite ICD implantation. TnT may be a useful marker for risk stratification of patients with CM prior to ICD implantation.

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Acute Effects of Biventricular Pacing on Noninvasive Parameters of Left Ventricular Systolic Function

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While invasive studies have shown that biventricular (BiV) pacing improves left ventricular (LV) function in selected heart failure patients, such techniques cannot be applied routinely. We sought to assess acute effects of BiV pacing by noninvasive techniques.

Methods: Sixteen patients enrolled in InSync trial (age 64 ± 9 years, 3 females, EF $< 35\%$ and QRS $> 130 \text{ ms}$) were studied one to 6 months after pacemaker implantation during BiV pacing, and while ventricular pacing was inhibited. Regional strains and displacements of the interventricular septum (IVS), LV free wall, and right ventricular (RV) free wall were obtained from Color Doppler tissue imaging in a four-chamber view (System Five, GE). Peak power index was calculated as a product of simultaneously acquired noninvasive blood pressure (Finapres, Ohmeda) and PW Doppler of the LV outflow tract.